DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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JUN 7 1999

Roger Kaufmann
Lafayette – Grand Hospital
3545 Lafayette
St. Louis, Missouri 63104

Re: Docket No. 99P-0344

Dear Mr. Kaufmann:

This responds to your citizen petition, dated February 3, 1999, in which Lafayette – Grand Hospital requests an exemption from compliance with the Performance Standard for Electrode Lead Wires and Patient Cables, as it applies to your Medtronic Teletrace 9408 telemetry transmitters. Your petition notes that the manufacturer no longer supports or services these devices, and no adapters could be identified to convert these devices for use with compliant electrode lead wires.

The Teletrace 9408 is a telephone electrocardiograph transmitter and receiver, and is included among ten specified devices for which electrode lead wires are required to comply with the performance standard after May 11, 1998. However, on August 3, 1998, the Food and Drug Administration (FDA) issued a letter to all user facilities, notifying them of their responsibility for compliance with the performance standard, and extending their compliance time frame until January 1, 1999. Your petition asks FDA for an exemption from the performance standard, to allow continued use of these telemetry devices through their normal life cycle, until they no longer perform their specified function.

The FDA is granting your request in part. However, rather than your requested exemption for an unspecified time period, we are granting a temporary variance until May 11, 2001, for the continued use of unprotected lead wires with these telemetry devices. This time frame is consistent with similar variances granted to other user facilities for similar devices. It will allow additional time to search for an acceptable supplier of adapters, and for retirement of some telemetry devices through attrition. We also note that Medtronic withdrew their service support for the device at the end of 1995. By the expiration of this approved variance, any remaining devices should be well past their normal expected life.

I trust that this response fully addresses your concerns. If additional information is required, please contact Stewart Crumpler in our Office of Compliance at (301) 594-4659.

Sincerely yours,

Linda S. Kahan
Deputy Director for Regulations and Policy
Center for Devices and Radiological Health

99P-0344

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